



RECEIVED

SEP 24 2002

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

Applicant(s): Elisabettni et al.  
Appl. No.: 10/044,234  
Filed: January 11, 2002  
Title: BICARBONATE-BASED SOLUTIONS FOR DIALYSIS THERAPIES  
Art Unit: 1616  
Examiner: Unknown  
Docket No.: DI-5782

Assistant Commissioner for Patents  
Washington, DC 20231

#7  
AKD  
9-27-02

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 37 C.F.R. 1.97, and 37 C.F.R. 1.98, Applicants request that a citation and examination of the references cited below, and on the attached PTO-1449 form, copies of which are enclosed, be made during the course of examination of the above-identified application for United States patent.

**FOREIGN PATENT DOCUMENTS**

<u>Document No.</u>	<u>Date</u>	<u>Country</u>
JP 56164113 -	12-17-81	Japan
EP 0 083 360 -	07-13-83	Europe
EP 0 165 933 B1 -	01-02-86	Europe
WO 86/03407 -	06-19-86	PCT
EP 0 209 607 -	01-28-87	Europe
WO 87/03809 -	07-02-87	PCT
EP 0 249 667 B1 -	12-23-87	Europe
EP 0 277 868 A2 -	08-10-88	Europe
EP 0 278 100 A2 -	08-17-88	Europe
EP 0 399 549 A1 -	11-28-90	Europe
0 399 918 A2 -	11-28-90	Europe
JP 2304026 -	12-17-90	Japan
0 417 478 A1 -	03-20-91	Europe
0 437 274 A1 -	07-17-91	Europe
EP 0 439 061 B1 -	07-31-91	Europe
JP 3195561 -	08-27-91	Japan

<u>Document No.</u>	<u>Date</u>	<u>Country</u>
WO 91/18610 ~	12-12-91	PCT
0 481 257 A1 ~	04-22-92	Europe
JP 5105633 ~	04-27-93	Japan
JP 6105905 ~	04-19-94	Japan
EP 0 613 688 A1 ~	09-07-94	Europe
EP 0 647 145 B1 ~	04-12-95	Europe
WO 95/19778 ~	07-27-95	PCT
JP 7252137 ~	10-03-95	Japan
WO 96/01118 ~	01-18-96	PCT
JP 8131542 ~	05-28-93	Japan
JP 8164199 ~	06-25-96	Japan
WO 97/05851 ~	02-20-97	PCT
JP 9087182 ~	03-31-97	Japan
JP 9110703 ~	04-28-97	Japan
EP 0 776 649 A2 ~	06-04-97	Europe
JP 9301875 ~	11-25-97	Japan
FR 2 753 099 ~	03-13-98	France
WO 98/10733 ~	03-19-98	PCT
JP 10201821 ~	08-04-98	Japan
JP 11004872 ~	01-12-99	Japan
WO 99/01144 ~	01-14-99	PCT
JP 11-9659 ~	01-19-99	Japan
JP 11-19178 ~	01-26-99	Japan
WO 99/09953 ~	03-04-99	PCT
DE 19748290 ~	05-06-99	Germany
EP 0 935 967 A2 ~	08-18-99	Europe
EP 1166787 ~	01-02-02	Europe

---

## **OTHER DOCUMENTS**

- Manahan et al., *Peritoneal Dialysis using bicarbonate-containing solution sterilized by ultrafiltration*, The International Journal of Artificial Organs, Vol. 14 no. 8, 1999, pp. 463-465.
- Murphy et al., *Use of an Artificial Kidney*, Vol. 40, 1952, pp. 436-444.
- Tjiang, Boen San, *A Clinical Study of Factors Governing its Effectiveness*, Peritoneal Dialysis, p. 76, Van Gorcum & Co., Assen, The Netherlands (1959).
- Feriani et al., *Short-Term Clinical Study with Bicarbonate-Containing Peritoneal Dialysis Solution*, Peritoneal Dialysis International, Vol. 13, pp. 296-301 (1993).
- The Merck Index, 12<sup>th</sup> Ed., Merck Research Laboratories, Whitehouse Station, NJ, 9 1472 (1996).
- Odel et al., *Peritoneal Lavage as an Effective Means of Extraenal Excretion. A Clinical Appraisal*, American Journal of Medicine, Vol. 9, 63-88 (1950).
- Schambye et al., *The Cytotoxicity of Continuous Ambulatory Peritoneal Dialysis Solutions with Different Bicarbonate/Lactate Ratios*, Peritoneal Dialysis International Vol. 13, Suppl. 2, Oct. 1-4, pp. S116-S118 (1994).
- Schambye et al., *Bicarbonate-versus Lactate-Based CAPD fluids: A Biocompatibility Study in Rabbits*, Peritoneal Dialysis International, Vol. 12, pp. 281-286 (1992).
- Simonsen et al., *Less Infusion Pain and Elevated Level of Cancer Antigen 125 by the Use of a New and More Biocompatible PD Fluid*, Advances in Peritoneal Dialysis, Vol. 12, pp. 156-160 (1996).
- Ing., et al., *Bicarbonate-Buffered Peritoneal Dialysis*, The International Journal of Artificial Organ, Vol. 8, No. 3, p. 121-124 (1985).
- Zhou et al., *Effects of an Acidic, Lactate-Based Peritoneal Dialysis Solution and its Euhydric, Bicarbonate-Based Counterpart on Neutrophilic Interacellular pH*, Int. J. Artif. Organs, Vol. 16, No. 12, pp. 816-819 (1993).
- American Society for Artificial Internal Organs, 1994 Abstracts, pp 110.
- Faller et al., *Loss of Ultrafiltration in Continuous Ambulatory Peritoneal Dialysis: A Role for Acetate*, Peritoneal Dialysis Bulletin, January-March 1984, pp 10-13.
- Ing et al., *Lactate-Containing Peritoneal Dialysis Solutions*, International J. of Artificial Organs, Vol. 16, No. 10, 1993, pp 688-693.
- Ing et al., *Lactate-Containing Versus Bicarbonate-Containing Peritoneal Dialysis Solutions*, Peritoneal Dialysis International, Vol. 12, pp 276-277.

Ing et al., *Preparation of Bicarbonate-Containing Dialysate for Peritoneal Dialysis*, International J. of Artificial Organs, Vol. 6, No. 4, 1983, pp 217-218.

Manahan et al., *Effects of Bicarbonate-Containing Versus Lactate-Containing Peritoneal Dialysis Solutions on Superoxide Production by Human Neutrophils*, Artificial Organs, Vol. 13, No. 6, 1989, pp. 495-497.


Richardson et al., *Bicarbonate, L-Lactate, and D-Lactate Balance in Intermittent Peritoneal Dialysis*, Peritoneal Dialysis Bulletin, Vol. 6, No. 4, 1986, pp. 178-185.

Yatzidis, Hippocrates, *A New Stable Bicarbonate Dialysis Solution for Peritoneal Dialysis: Preliminary Report*, Peritoneal Dialysis International, Vol. 11, pp. 224-227.

An early and favorable consideration of this matter is respectfully requested.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

A handwritten signature in black ink, appearing to read 'BY' followed by a stylized, cursive signature.

Robert M. Barrett  
Reg. No.30,142  
P.O. Box 1135  
Chicago, Illinois 60690-1135  
Phone: (312) 807-4204

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c))			Docket No. DI-5782
In Patent Application Of: Elisabettini et al.			
Serial No. 10/044,234	Filing Date January 11, 2002	Examiner Unknown	Group Art Unit 1616
Title: BICARBONATE-BASED SOLUTIONS FOR DIALYSIS THERAPIES			
Address to: Assistant Commissioner for Patents Washington, D.C. 20231			
<b>37 CFR 1.97(b)</b>			
1. <input checked="" type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.			
<b>37 CFR 1.97(c)</b>			
2. <input type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:			
<input type="checkbox"/> the statement specified in 37 CFR 1.97(e);			
OR			
<input type="checkbox"/> the fee set forth in 37 CFR 1.17(p).			

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
DI-5782

Re Application: Elisabettini et al.

Serial No.  
10/044,234

Filing Date  
January 11, 2002

Examiner  
Unknown

Group Art Unit  
1616

**BICARBONATE-BASED SOLUTIONS FOR DIALYSIS THERAPIES**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Assistant Commissioner is hereby authorized to charge and credit Deposit Account No. \_\_\_\_\_ as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of \_\_\_\_\_
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.

**Certificate of Transmission by Facsimile\***

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (F

(Date)

Signature

Typed or Printed Name of Person Signing Certificate

**Certificate of Mailing by First Class Mail**

I certify that this document and fee is being deposited on 09-18-2002 with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Signature of Person Mailing Correspondence

Robert J. Buccieri

Typed or Printed Name of Person Mailing Certificate

\*This certificate may only be used if paying by deposit account.

Dated: September 18, 2002

Signature

Robert M. Barrett

Reg. No. 30,142

BELL, BOYD & LLOYD LLC

P.O. Box 1135

Chicago, IL 60690-1135

Ph ne: 312/807-4204

CC:

SEP 23 2002

**TRANSMITTAL LETTER**  
(General - Patent Pending)

Docket No.  
DI-5782

In Patent Application Of: Elizabettni et al.

Serial No.  
10/044,234

Filing Date  
January 11, 2002

Examiner  
Unknown

Group Art Unit

Title: BICARBONATE-BASED SOLUTIONS FOR DIALYSIS THERAPIES

RECEIVED  
SEP 24 2002  
TECH CENTER 1600/2900

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith is:

Transmittal of Information Disclosure Statement (duplicate); Supplemental Information Disclosure Statement (4 pgs.); Supplemental Information Disclosure Citation PTO Form 1449 (4 pgs.); 62 references; return receipt postcard.

in the above identified application.

- ☒ No additional fee is required.
- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Assistant Commissioner is hereby authorized to charge and credit Deposit Account No. 02-1818 as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of \_\_\_\_\_
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.

  
Signature

Dated: September 18, 2002

Robert M. Barrett  
Reg. No. 30,142

BELL, BOYD & LLOYD LLC  
P.O. Box 1135  
Chicago, IL 60690-1135  
Phone: 312-807-4204

I certify that this document and fee is being deposited on 09-18-2002 with the U.S. Postal Service as first class mail under 39 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

  
Signature of Person Mailing Correspondence

Robert J. Buccieri

Typed or Printed Name of Person Mailing Correspondence

CC: